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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/070,271	06/13/2002	Shane Willard Nickson	22748/1	2417	
21710 75	590 08/26/2003				
BROWN, RUDNICK, BERLACK & ISRAELS, LLP.			EXAMINER		
BOX IP, 18TH ONE FINANCI			PHAM, HUONG Q		
BOSTON, MA	A 02111		ART UNIT	PAPER NUMBER	
			3764 DATE MAILED: 08/26/2003	13	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>\$</b> 1		Application I	No.	Applicant(s)	Ool		
Office Action Summary		10/070,271		NICKSON, SHANE WILLARD			
		Examiner		Art Unit			
		Huong Q. Pha		3764			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)	Responsive to communication(s) filed on	•					
2a)⊠		— nis action is no	n-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>13-15 and 17-25</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) 🗌	5) Claim(s) is/are allowed.						
6)⊠	Claim(s) <u>13-15,17-25</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
•	Claim(s) are subject to restriction and/o	or election requ	uirement.				
	on Papers						
•	The specification is objected to by the Examine						
10) 🔲 -	The drawing(s) filed on is/are: a)☐ acception						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s)							
2) Notic	re of References Cited (FTO-032)  e of Draftsperson's Patent Drawing Review (PTO-948)  mation Disclosure Statement(s) (PTO-1449) Paper No(s)	-,		Patent Application (PT			

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the connection between the sole plate and the strut, and the connection between the strapping member and the anterior longitudinal stiffener.

The remaining claims are objected to for being dependent on the rejected claim 13.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1) Claims 13, 14, and 17-24 are rejected under 35 U.S.C. 103(a) as obvious over Hall in view of the publication WO 95/31950. As for claim 13, Hall shows very claimed feature of claims 13 including a strapping member 14, an anterior longitudinal stiffener 10, a strut 30 (32, 36, 34), a sole plate 40. Note

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that Hall teaches that "When desire, the shape or thickness of the yoke or stirrup can be controlled to control the amount of flexion between the foot base and the leg support (column3, lines 31-34), and ".... a unitary construction permitting flexure of the foot relative to the ankle without the use of hinged members and the like" (column 3, lines 55-57). Thus, Hall teaches that the thickness or shape of the strut 30 (32, 36, 34) can be varied in order to achieve the desired amount of flexion between the anterior longitudinal stiffener 10 and the foot base 40. Note that the brace of Hall is made of thermoplastic material. While Hall does not teach the reinforced resin materials for his brace as recited in claim 13, the publication WO 95/31950 teaches a joint orthosis with a strapping member 1, ioined reinforcement elements 2A, 2B made of reinforced resin materials having different degree of rigidity, and which can be applied to an ankle joint ( Page 1. lines 15-17; page 2, lines 35, 36). In view of this teaching of the publication WO 95/31950, in order to provide or achieve the amount of flexion between the stiffener 10 and the foot base 40 as suggested by Hall, it would have been obvious to an ordinary skill in the art at the time the invention was made to substitute the thermoplastic material of the stiffener 10 of Hall with the rigid reinforced resin material, and with the resilient or flexible reinforced resin material for the strut 30. As for claim 14, note that the publication WO 95/31950 teaches two joined areas of a brace made of two different materials with different degrees of rigidity (to provide the desired flexibility for the joined area): the use of carbon fibre reinforced plastic resin for areas of the brace which need to be very rigid, and the use of fibreglass reinforced plastic resin for areas of the brace

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which need to be more flexible. As for claim 17, note the strap 18 of Hall. Note that the provision of plurality of straps for securing a brace to the leg of a wearer is very well-known in the art, and it would have been obvious to an ordinary skill in the art at the time the invention was made to provide more than one strap for the brace of Hall in order to firmly secure the brace to the leg of a wearer. As for claim 18, note that the strapping of Hall is made of thermoplastic material, and note that "soft" is a relative term. A material which is "soft" to one person may be considered to be "hard" to another person. As for claims 19-21, note that the strut of Hall is encased in a sleeve of plastic material. As for claim 22, note the fastener 26 of Hall, and note that the phrase " ... said anterior ... is longitudinal movable...." is only a functional statement without any positive recitation of necessary structure to support this recited function, and therefore is not given any weight. As for claim 23, note that the anterior longitudinal stiffener 2B of the publication WO 95/31950 is disposed on the inside portion of the strapping member 1. As for claim 24 and note that the strapping member 1 of brace of the publication WO 95/31950 has a channel ( where the reinforced element 2A, 2B is embedded).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable 3) over Hall as applied to claims 13, 14 and 17-24 above, and further in view of Willner et al. While Hall does not mention about a sole plate with different portions having different strength and flexibility. Willner et al teaches a footplate 5 with this structure. In view of the teaching of Willner et al, it would have been

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obvious to an ordinary skill in the art at the time the invention was made to provide the foot pad 40 of Hall with different portions having different strength and flexibility in order to allow flexion of the foot and promote a more natural gait.

unpatentable over Hall in view of DeToro and/or DiBenedetto. Note that DeToro and DiBenedetto clearly teach a channel with an opening for the stiffener to allow adjustability for a brace. In view of the teaching of DeToro and/or DiBenedetto, it would have been obvious to an ordinary skill in the art at the time the invention was made to provide a channel and an opening, as recited in claims 24-25, for the brace of Hall in order to provide adjustability and good fit. The provision of an adjusting means for a brace in order to provide a good fit for a wearer is well known in the art, and is only a matter of obvious engineering design choice, and therefore is not patentable over prior art.

Applicant's arguments filed on 6/24/03 have been fully considered but they are not persuasive. Note the comments relative to the claims above.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire

THREE MONTHS from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q. Pham whose telephone number is (703) 305-5129. The examiner can normally be reached on 6:30 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (703) 308 - 2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

NICHOLAS D. LUCCHESI SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

August 24, 2003